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| EXAMINER |
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CHU, YONG LIANG

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| ART UNIT | PAPER NUMBER |
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1626

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08/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,115

Applicant(s)

KOLESNIKOV ET AL.

Examiner

Yong Chu

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 5-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☒ Claim(s) 1-4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-10 are pending in the instant application.

Priority

This application is a 371 of PCT/US03/38635 filed on 12/03/2003, and claims the benefit of U.S. Provisional Patent Application No. 60/430,981 filed on 12/03/2002.

Response to Lack of Unity

Applicants' election with traverse of Group VIII (claims 1-4) and elected species of compound 123 on page 26 of the Specification in the reply filed on 07/16/2007 is acknowledged. Applicant's traversal on the ground that there is no undue burden on Office on a complete search has been considered, and found not persuasive, because whole application lacks of unity of invention. Please refer to the previous Office action for the explanation. Accordingly, the restriction requirement is maintained.

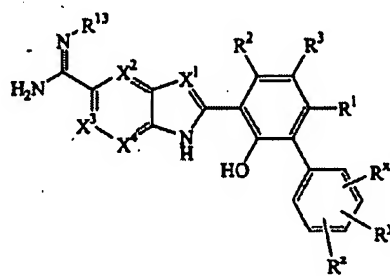
Status of the Claims

Claims 5-10 are further withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR 1.142(b) due to the restriction requirement. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search

considerations. In addition, a reference that anticipates one invention would not render obvious the other invention.

Elected and Examined Subject Matter

The scope of the invention of the elected subject matter and the examined subject matter is as follows:



A compound of the Formula (I), wherein:

X^1 is $-N-$; X^2 , X^3 , and X^4 are $-CR^5-$, wherein R^5 is H;

R^1 , R^2 , R^{13} , and R^y are H;

R^3 is H, alkyl, $-CONR^7R^8$, $-CH_2CONR^9R^{10}$, or $-C(CH_3)_2CONR^9R^{10}$, wherein $R^7 - R^{10}$ as defined in claim 1;

R^x is H, or $-OH$ at the 2'-position; and

R^z is H, aminosulfonyl, or ureidomethyl at the 5'-position, or a composition comprising the said compound in claim 1.

As a result of the election and the corresponding scope of the invention identified supra, the remaining subject matter of claims 1-4 is withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups, which are chemically recognized to differ in structure, function, and reactivity.

Specification

The first paragraph of the specification does not contain continuing data to which the instant specification claims benefit from. An appropriate amendment is required.

Claim Rejections - 35 USC § 102(b)

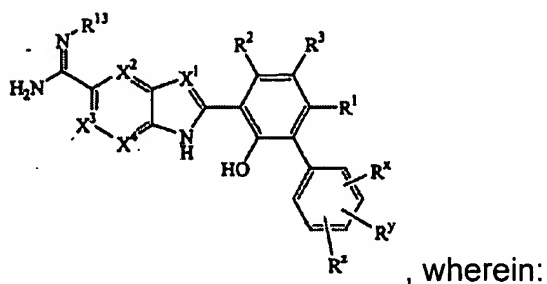
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102 (b) as being anticipated by Allen et al., PCT publication WO2000-035886 (the '886 publication).

Applicants' claims relate to a compound of the Formula (I)



X^1 is $-N-$; X^2 , X^3 , and X^4 are $-CR^5-$, wherein R^5 is H;

R^1 , R^2 , R^{13} , and R^y are H;

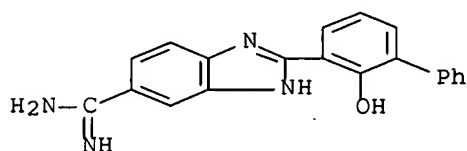
R^3 is H, alkyl, $-\text{CONR}^7\text{R}^8$, $-\text{CH}_2\text{CONR}^9\text{R}^{10}$, or $-\text{C}(\text{CH}_3)_2\text{CONR}^9\text{R}^{10}$, wherein $R^7 - R^{10}$ as defined in claim 1;

R^x is H, or $-\text{OH}$ at the 2'-position; and

Art Unit: 1626

R^z is H, aminosulfonyl, or ureidomethyl at the 5'-position, or a composition comprising the said compound in claim 1.

The '886 publication (published on 06/22/2000) disclose a compound



2-(2-Hydroxy-biphenyl-3-yl)-3H-benzoimidazole-5-carboxamide;

(CAS

RN 277311-06-5) at page 179, lines 28-29. This compound was disclosed as a component of as inhibitors of serine proteases, Urokinase, Fxator Xa, and Factor VIIa. Therefore, the prior art teaching anticipates the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

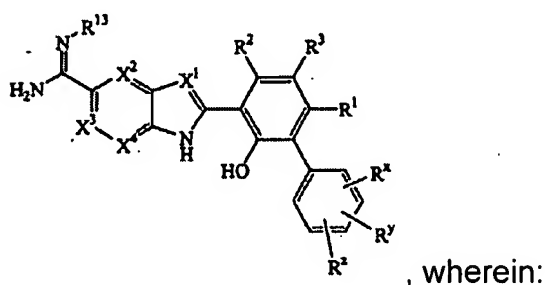
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 are rejected under 35 U.S.C. 103 (a) as unpatentable over the '886 publication.

Applicants' claims relate to a compound of the Formula (I)



X¹ is -N-; X², X³, and X⁴ are -CR⁵-, wherein R⁵ is H;

R¹, R², R¹³, and R^y are H;

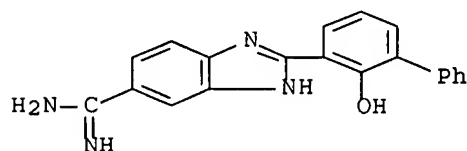
R³ is H, alkyl, -CONR⁷R⁸, -CH₂CONR⁹R¹⁰, or -C(CH₃)₂CONR⁹R¹⁰, wherein R⁷ - R¹⁰ as defined in claim 1;

R^x is H, or -OH at the 2'-position; and

R^z is H, aminosulfonyl, or ureidomethyl at the 5'-position, or a composition comprising the said compound in claim 1.

Determination of the scope and content of the prior art (MPEP §2141.01)

The '886 publication (published on 06/22/2000) disclose a compound



2-(2-Hydroxy-biphenyl-3-yl)-3H-benzoimidazole-5-carboxamide;

(CAS

RN 277311-06-5) at page 179, lines 28-29. This compound was disclosed as a component of as inhibitors of serine proteases, Urokinase, Fxator Xa, and Factor VIIa. Therefore, the prior art teaching anticipates the instant claims.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the '886 publication and the instantly claimed compounds, is that the reference teaches the compounds with R^3 as -H, but does not teach compounds wherein R^3 is alkyl, such as $-CH_3$.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

To those skilled in the chemical art, one homologue with R^3 as -H is not such an advance over adjacent member of series as R^3 as alkyl as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members, especially they have the same utility as a inhibitor of Fxator Xa, and/or Factor VIIa. *In re Henze*, 85 USPQ 261 (1950). Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

Double Patenting

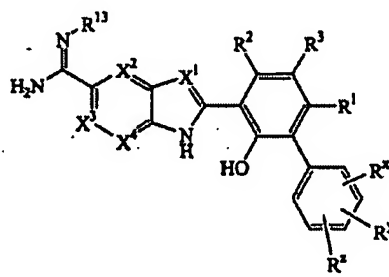
The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Art Unit: 1626

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of the '200 patent. More specifically, the compound in claim 6, lines 18-19, column 103. Although the conflicting claims are not identical, they are not patentably distinct from each other because Applicants'



claims relate to a compound of the Formula (I)

X^1 is $-N-$; X^2 , X^3 , and X^4 are $-CR^5-$, wherein R^5 is H;

R^1 , R^2 , R^{13} , and R^y are H;

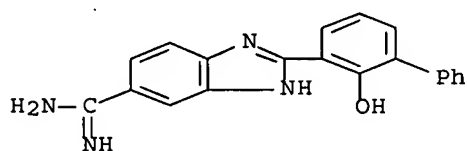
R^3 is H, alkyl, $-CONR^7R^8$, $-CH_2CONR^9R^{10}$, or $-C(CH_3)_2CONR^9R^{10}$, wherein $R^7 - R^{10}$ as defined in claim 1;

R^x is H, or $-OH$ at the 2'-position; and

R^z is H, aminosulfonyl, or ureidomethyl at the 5'-position, or a composition comprising the said compound in claim 1.

Determination of the scope and content of the prior art (MPEP §2141.01)

The '200 patent disclose a compound



2-(2-Hydroxy-biphenyl-3-yl)-3H-benzoimidazole-5-carboxamide;

(CAS

RN 277311-06-5). This compound was disclosed as a component of as inhibitors of serine proteases, Urokinase, Fxator Xa, and Factor VIIa. Therefore, the prior art teaching anticipates the instant claims.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the '200 patent and the instantly claimed compounds, is that the reference teaches the compounds with R^3 as -H, but does not teach compounds wherein R^3 is alkyl, such as $-CH_3$.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

To those skilled in the chemical art, one homologue with R^3 as -H is not such an advance over adjacent member of series as R^3 as alkyl as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members, especially they have the same utility as a inhibitor of Fxator Xa, and/or Factor VIIa. *In re Henze*, 85 USPQ 261 (1950). Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

Claim Objections

Claims 1-4 are objected to for containing elected and non-elected subject matter. The elected subject matter has been identified supra.

Claim 3 is objected to for minor informality on R^z , wherein "...at the 5 position.." should be "...at the 5' position..".

Conclusion

- Specification is objected to.


- Claims 1-4 are objected to.
- Claims 1-4 are rejected.

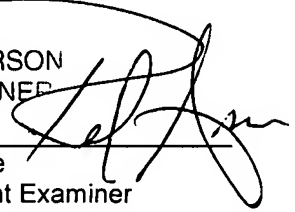
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Yong Chu, Ph.D.
Patent Examiner
Art Unit 1626

REBECCA ANDERSON
PRIMARY EXAMINER

Joseph K. McKane
Supervisory Patent Examiner
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